## **CLAIMS**

## We claim,

- 1. A method of treating neointimal hyperplasia in a subject in need thereof, comprising administering an interleukin-1 (IL-1) antagonist to the subject such that neointimal hyperplasia is treated.
- 2. The method of claim 1, wherein the neointinal hyperplasia is restenosis.
- 3. The method of claim 1, wherein the neointimal hyperplasia is atherosclerosis.
- 4. The method of claim 1, wherein the neointimal hyperplasia is vascular access dysfunction.
- 5. The method of claim 1, wherein the neointimal hyperplasia is caused by surgical stenting, angioplasty, or vascular grafting.
- 6. The method of claim 1, wherein the IL-1 antagonist blocks IL-1 activity or expression.
- 7. The method of claim 6, wherein the IL-1 antagonist is selected from the group consisting of an anti-IL-1 antibody or antibody fragment, an anti-IL-1R1 antibody or antibody fragment, an anti-IL-1R2 antibody or antibody fragment, an IL-1 trap, IL-1Ra, an antisense molecule, an inhibitory ribozyme designed to catalytically cleave gene mRNA transcripts encoding IL-1α, IL-1β, IL-1R1, IL-1RAcp, and a short interfering RNA (siRNA) molecule.
- 8. The method of claim 7, wherein the IL-1 trap comprises (i) one or more IL-1 receptor components or fragments thereof, (ii) one or more antibody or antibody fragments specific to an IL-1 ligand or an IL-1 receptor, or fragments thereof, or a combination of receptor components and antibody fragments, and (iii) a multimerizing component.

- 9. The method of claim 8, wherein the multimerizing component is an immunoglobulin-derived domain.
- 10. The method of claim 1, wherein the subject is a human.
- 11. The method of claim 1, wherein the administration is subcutaneous, intramuscular, intranasal, intraarterial, intravenous, topical, transvaginal, transdermal, transanal administration or oral routes of administration.
- 12. A pharmaceutical composition comprising an IL-1 antagonist and a pharmaceutically acceptable carrier.
- 13. The pharmaceutical composition of claim 12, wherein the IL-1 antagonist blocks IL-1 activity or expression.
- 14. The pharmaceutical composition of claim 13, wherein the IL-1 antagonist is selected from the group consisting of an anti-IL-1 antibody or antibody fragment, an anti-IL-1R1 antibody or antibody fragment, an anti-IL-1RAcp antibody or antibody fragment, an IL-1 trap, IL-1Ra, an antisense molecule, an inhibitory ribozyme designed to catalytically cleave gene mRNA transcripts encoding IL-1α, IL-1R1, IL-1RAcp, and a short interfering RNA (siRNA) molecule.
- 15. The pharmaceutical composition of claim 14, wherein the IL-1 trap comprises (i) one or more IL-1 receptor components or fragments thereof, (ii) one or more antibody or antibody fragments specific to an IL-1 ligand or an IL-1 receptor, or fragments thereof, or a combination of receptor components and antibody fragments, and (iii) a multimerizing component.
- 16. The pharmaceutical composition of claim 15, wherein the multimerizing component is an immunoglobulin-derived domain.

- 17. A method of preventing neointimal hyperplasia in a subject in need thereof, comprising administering a cytokine antagonist to the subject such that neointimal hyperplasia is prevented.
- 18. The method of claim 17, wherein the neointinal hyperplasia is restenosis, atherosclerosis, or vascular access dysfunction.
- 19. The method of claim 18, wherein the neointimal hyperplasia is caused by surgical stenting, angioplasty, or vascular grafting.
- 20. An article of manufacturing, comprising:
  - (a) packaging material; and
- (b) a pharmaceutical gent contained within the packaging materi9al; wherein the pharmaceutical agent comprises at least one interleuking-1 (IL-1) trap of the invention and wherein the packaging material comprises a label or package insert which indicates the IL-1 trap can be used for the treatment of neointimal hyperplasia.